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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/971,172 11/14/97 GOODMAN

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EXAMINER

TURNER, S

ART UNIT	PAPER NUMBER
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1644

19

DATE MAILED:

05/10/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/971,172

Applicant(s)

Goodman

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit

1644



☒ Responsive to communication(s) filed on 2-16-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 10-67 is/are pending in the application.

Of the above, claim(s) 43-49 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 10-42 and 50-67 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **Response to Amendment**

1. The Art Unit of U.S. Patent application SN 08/971,172 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1644.
2. The amendment and declarations filed under 37 CFR 1.131 and 1.132 filed 8-20-99 have been entered into the record and have been fully considered.
3. Claims 43-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.
4. The examiner acknowledges applicants request for rejoinder of method claims 43-49 upon allowability, however the request is not granted because the claims are not in condition for allowance.
5. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

### **Rejections Maintained**

6. Claims 10-42 and 50-67 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

Applicants argue that the phrase "flanked by fewer than 500 bp of native flanking sequence" is clear and definite to those of ordinary skill in the art in view of the specification and

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further point to the specification at p. 19, lines 27-33 for clarification of the encompassed sequences. Applicants conclude that this usage (p. 19, lines 27-33) clearly conveys to those skilled in the art that (a) a strand “flanked by fewer than 500 bp of native flanking sequence” is contiguous with, on at least one end, fewer than 500 bp of native flanking sequence; (b) fewer than 500 bp includes zero bp and (c) native flanking sequence is sequence to which the strand is joined on a natural chromosome. Applicants further state that native flanking sequences are readily determined from corresponding natural chromosome sources which are identified in the specification e.g., p. 4, lines 1-3. Applicants submit a declaration under 37 CFR 1.132 to demonstrate the the claims are definite.

Applicant's arguments and declaration under 37 USC 1.132 filed 2-16-00 have been fully considered but they are not persuasive. Applicants specification does not define the nucleotide sequences encompassed by “native flanking sequence.” Applicants specification does not define native flanking sequence as that sequence to which the strand is joined on a natural chromosome. The specification only supports native flanking sequences of a certain size and flanking sequence which is other than that which it is joined to on a natural chromosome. Applicants arguments that one of ordinary skill in the art can readily determine the sequences from corresponding natural chromosome sources also does not further define the nucleotide sequences. In contrast, the description leads the skilled artisan to believe the intended nucleotides to be encompassed are any of the (native) nucleotide sequences within the natural genome of any of the organisms of page 4, including allelic variants wherein the specified length is fewer than 500 bp. The

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rejection is maintained as the nucleotide sequences encompassed remain vague and indefinite. Applicants declaration refers only to the definitions discussed above and thus also does not aid the skilled artisan in defining the nucleotides encompassed by native flanking sequences. The examiner notes that applicants also state that no flanking sequences need be present as zero is included within the scope of the claim. Thus, the limitation native flanking sequences does not appear to be a structural or functional limitation of the claims as previously interpreted by the examiner. This appears to further compound the confusion regarding the specific nucleotides encompassed by the claims. Clarification is required.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 10-11, 19-20, 28-29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson et al., Nature 368(6466):32-38, 1994.

Applicants argue that the examiner appears to rely on a sequence deposit designated 001632 which corresponds to U88183 reportedly released on April 21, 1997 and submit a declaration under 37 CFR 1.131 stating that applicants sequenced their U88183 clone prior to April 1997.

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Applicants declaration under 37 CFR 1.131 submitted 2-16-00 has been fully considered but is not persuasive. The declaration lacks a statement regarding the location in this country or in a NAFTA or WTO member country. Further the declaration is ineffective to overcome the reference of record, namely Wilson et al, dated 1994, cited under 102(b) which may not be overcome by a declaration under 37 CFR 1.132. The alignment clearly indicates the sequence overlap between the residues of SEQ ID NO:6 which is an amino acid sequence and predicted residues of Wilson et al, 1994. The corresponding nucleotides of U8813 also overlap with the reference of record which discloses 2.2 Mb of contiguous nucleotide sequence from chromosome III of *C. elegans*. As the nucleotides disclosed by Wilson correspond to the nucleotides of instant SEQ ID NO:6 the invention is anticipated. Further, the claimed invention only requires subsequences of 12 nucleotides in length.

#### **New Rejections Based on Amendment**

9. Claims 10-42 and 50-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses nucleic acid SEQ ID NO's: 1, 3, 5, 7, 9 and 11 which correspond to Robo nucleic acids. These SEQ ID NO's meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to or encompass genomic sequences, mutated sequences, allelic variants, and splice variants, such as native flanking

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sequences. None of these sequences meets the written description provision of 35 USC 112, first paragraph.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that, “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is for purposes of the ‘written description’ inquiry, whatever is now claimed.” (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO’s:1, 3, 4, 7, 9 and 11 of the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed nucleic and amino acid sequences and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific nucleic acids are required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF’s were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO’s:1, 3, 5, 7, 9 and 11, but not the full breadth of claims meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that

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Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

10. Claims 10-42 and 50-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 and 50 exclude portions of SEQ ID NOs:7-8 and 11-12, however dependent claims 11-42 and 51-67 recite subsequences of SEQ ID NO:7, 8 and 11. Thus, the metes and bounds of the claims are indefinite because they are contradictory. It is not clear which residues are included or excluded. Claims 11-42 and 51-67 as they depend from claims 10 and 50 should further limit the nucleotides and/or amino acids encompassed. Clarification is required.

11. Claim 51 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No:AA499103 which shares 100% identity with SEQ ID NO:11 over its entire length. Thus AA499103 anticipates the nucleic acids of claims 10-12, 25-28 and 50.

12. Claims 10-11, 22-23, 50-52 and 62-64 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No:Z95705, May 25, 1997 which shares 100% identity with SEQ ID NO:7, residues 1016-1891 and 1901-4956 over its entire length. Thus Z95705 anticipates the nucleic acids of claims 10-11, 22-23, 50-52 and 62-64.

13. Claims 50 and 65-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. H19148, July 2, 1995.

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Genbank Accession No. H19148 teaches SEQ ID NO:9 residues 30- 359 with 100% identity, see alignment with residues 856-1185 of H19148, and thus anticipates claims 50 and 65-67 as claimed.

14. Claim 56 is rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. I24739, October 15, 1996.

Genbank Accession No. I24739 teaches SEQ ID NO:3 residues 945-968, see alignment with residues 3259-3283 of I24739, and thus anticipates claims 56 as claimed.

15. Claims 29, 31 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genbank Accession No:Z95705 as applied to claims 10-11, 22-23, 50-52 and 62-64 above, and further in view of Sambrook et al, Molecular Cloning, Cold Spring Harbor Labs, 1989, 16.1-16.16.

As set forth above Genbank Accession No:Z95705 sets forth SEQ ID NO:7 residues 1016-1891 and 1901-4956 in 100% entirety. However, Genbank Accession No:Z95705 does not teach the nucleic acids in a vector and host cell for the production of polypeptides as claimed in claims 29, 31 and 38. The relative skill in the art is reflected by Sambrook et al which teach the expression of cloned DNA in mammalian cells using vector nucleic acids. Such vector and host cell materials were readily available, at the time of the invention. The skilled artisan is well apprised of such cloning techniques widely known in the art. It would have been prima facie obvious for one of skill in the art knowing the DNA of Z95705, to substitute the DNA molecules of Z95705 into a vector and host cell using the techniques of Sambrook et al to clone the

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sequences into cells for the replication of the claimed nucleic acids, expression of the polypeptides, and subsequences thereof. One would have been motivated to clone such nucleic acids into a polypeptide expression vector in order to study the protein produced thereby from the cells. Further, one would have expected success based on the high skill in the art, the teachings of Sambrook et al and the publicly availability of numerous cell lines capable of expression. The knowledge of the appropriate DNA sequence taught by Z95795 in the prior art thus renders the claimed nucleic acids, vectors, host cells and method of producing the polypeptides obvious.

#### **Status of Claims**

16. No claims are allowed.


#### **Conclusion**

17. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.  
May 8, 2000

  
CHRISTINA Y. CHAN  
SUPERVISORY PATENT EXAMINER  
GROUP 1800/1644